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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/685,199

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Stefan Petry

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4176

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7590

06/26/2006

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EXAMINER

COPPINS, JANET L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/685,199	<b>Applicant(s)</b> PETRY ET AL.	
	<b>Examiner</b> Janet L. Coppins	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/01/03</u> <u>8/01/04</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-13 are pending in the instant application.

#### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statements, filed November 10, 2003, and August 9, 2004, have been considered by the Examiner. Please refer to the signed copies of Applicants' PTO-1449 forms submitted herewith.

#### ***Election/Restrictions***

3. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to compounds and their pharmaceutical compositions according to formula I, classified in various subclasses of classes 546 and 548. A further election of a single disclosed species will be required if this Group is elected.
- II. Claim 9, drawn to a process of preparation, classified in various subclasses of classes 546 and 548.
- III. Claim 10, drawn to a medicament containing a compound of formula I, classified in class 514, various subclasses.
- IV. Claims 11 and 12, drawn to methods of using the medicament, classified in various subclasses of class 514,

- V. Claim 13, drawn to a method of using a compound of claim 1, classified in various subclasses of class 514.

***The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:***

4. Invention I is related to Invention II as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another materially different process as demonstrated in the Katritzky et al journal article, please refer to the reaction Scheme 1 on page 230, wherein a benzotriazole compound is prepared.
5. Invention I is related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process as claimed can be practiced with another materially different product since there are many known methods for treating non-insulin-dependent diabetes mellitus, including for example, administering sulfa-containing drugs. Therefore separate search conditions are involved, which would impose a burden if unrestricted.
6. Inventions II, IV, and V are related as process of making and process of using the product. Since the product is not allowable, restriction is proper between said method of making and method of using. These methods are directed to different statutory classes of invention and

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the practice of one of Inventions II, IV, or V would not result in the practice of the other Invention, i.e. treating non-insulin-dependent diabetes is not a process that prepares *per se* the compounds of the instant invention.

7. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

8. During a telephone conversation with Mr. Irving Newman, Reg. No. 22,638, on Friday, June 9, 2006, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8, drawn to compounds and their compositions. Affirmation of this election must be made by applicant in replying to this Office action. Accordingly, claims 9-13 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. (a) Claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Simons et al, Research Development Journal. Simons et al teach triazole compounds according to formula I on page 1, and teach preferred compounds with a benzotriazole ring for "Z," please refer to formula II on page 2. Simons et al specifically discuss compounds wherein, "...R<sup>1</sup> and R<sup>2</sup>... may be taken together with the nitrogen to which they are attached to form a heterocyclic ring, such as... piperidine, pyrrolidine...etc." (please refer to page 1). Therefore Simons et al teach the same compounds as instantly claimed in formula I wherein "n" is 0 or 1 and R1-R8 are hydrogen.

(b) Claims 1-4 also rejected under 35 USC 102(b) as being anticipated by U.S. Pat. No.s 4,255,510, and 4,256,881, both to Simons et al. The '510 patent teaches benzotriazole compounds according to formula II in column II wherein, "...R<sup>1</sup> and R<sup>2</sup>... may be taken together with the nitrogen to which they are attached to form a heterocyclic ring, such as... piperidine, pyrrolidine...etc." The '881 patent teaches benzotriazole compounds according to formula I in column 1 wherein, "...R<sup>1</sup> and R<sup>2</sup>... may be taken together with the nitrogen to which they are attached to form a heterocyclic ring, such as... piperidine, pyrrolidine...etc." Therefore both patents specifically teach the same compounds as instantly claimed wherein "n" is 0 or 1 and R1-R8 are hydrogen.

### ***Claim Objections***

11. Claims 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

12. In conclusion, claims 1-13 are pending in the instant application, claims 9-13 are currently withdrawn from consideration, claims 1-4 are rejected, and claims 5-8 are objected to.


***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins  
June 17, 2006

  
Joseph K. McKane  
SPE, Art Unit 1626